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Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Published review of independent double checks shouldn't dissuade providers from using them judiciously

A recent systematic review of the effectiveness of double checking to reduce medication administration errors, published by Australian researchers in *BMJ Quality & Safety,* clearly demonstrates an overall lack of high-quality studies on the subject.[1] However, the authors also conclude that there is insufficient evidence that double versus single checking of medications prior to administration is associated with lower rates of medication errors or reduced harm. After careful examination and thorough consideration of the recent systematic review, ISMP respectfully concludes that little evidence was provided that should cause healthcare providers to abandon the use of judicious and well-placed independent double checks for selected high-alert medications. Instead, ISMP continues to believe that the selective and proper use of manual independent double checks plays an important role in medication safety.[2]

Our primary concerns with the recent systematic review are outlined below and are largely associated with limitations in the reviewed studies and disagreement with some of the conclusions drawn by the authors from these studies. Many of the study limitations are described by the authors. Yet, without careful consideration of the findings, we worry that the authors' conclusion—that there is insufficient evidence to support the double-check processes—may incorrectly dissuade healthcare providers from the judicious and proper use of independent double checks, as described in our June 6, 2019, newsletter[2] and summarized in **Table 1** (page 2).

Limitations in the Studies

Quality of the Studies Reviewed

Thirteen studies spanning 1992 to 2018 met the authors' inclusion criteria for the systematic review and were part of the analysis. However, the authors point out that study quality varied, and 10 of the 13 studies reviewed were rated as poor- or fair-quality studies based on criteria from the National Institutes of Health.[3] Many were underpowered and failed to provide meaningful results. Five of the studies had small study populations and/or low error rates, making it difficult to assess the association between double checking and medication error prevention. Five studies also relied completely or in part on self-reports or incident report data to measure medication errors, likely resulting in a large number of undetected and uncountable errors.

Only 3 of the reviewed studies were determined to be good-quality studies based on criteria from the National Institutes of Health. One of these studies only reported double checking compliance rates. The two other good-quality studies that evaluated effectiveness found a positive association between double checking and a reduction in medication errors. In one, an international observational study, double checking was significantly associated with a lower odds of any medication error.[4] In the other, a US randomized controlled simulation study, the use of a double check was found to be superior to a single check for detecting a relatively straightforward wrong vial error.[5] The double check was also more effective than the single check at detecting a more complex, weight-based dosing error, although this effect was less pronounced. All 3 good-quality studies used direct observation to identify medication error rates and/or compliance rates.

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SAFETY briefs

Products from Teva Canada have confusing expiration dates. A hospital pharmacy recently received a package of rizatriptan 10 mg tablets manufactured by Teva Canada. Pharmacy staff noticed a confusing expiration date (AL-2021) on the outer carton and each unit dose package (**Figure 1**). Teva USA was contacted and confirmed that a 2-letter abbreviation, based on French language abbreviations for the month, may be utilized for products manufactured by Teva Canada and are approved for sale in the US. The French abbreviations are not necessarily the same as the first 2 letters of that month. Teva's nystatin oral tablets are another product that bears this expiration date format.

Figure 1. Few US practitioners would understand this expiration date (April 30, 2021, bottom) on the side panel of rizatriptan packaging (top).

Table 1 (page 2) lists the abbreviations used by Teva Canada, with the names of the months in French and English. The expiration date is the last day of the month. These abbreviations are accepted by Health Canada in both official languages, French and English (www.ismp.org/ext/309). However, of concern in the US is that MA could be considered as March rather than May, and JN as January rather than June.

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Almost Half of the Studies Evaluated Only Compliance Rates

Six of the 13 studies included in the systematic review provided double-checking adherence rates but did not test for an association between double checking and medication administration errors. Thus, almost half of the studies included in the systematic review could not inform an evaluation of the effectiveness of double checking—they could only inform the question of whether double checks were being done, as required.

Independent Versus Primed Double Checking

As the authors pointed out, most of the studies investigating double checking did not differentiate between independent and primed double checking. Independent double checking requires two people to separately check the targeted components of the work process, without knowing the results of their colleague. Primed double checking involves two people working together or influencing the checking process by suggesting what

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Table 1. ISMP Recommendations for Manual Independent Double Checks[2]

Use Independent Double Checks Judiciously
■ Independent double checks should only be used for very select high-risk tasks, vulnerable patients, or select high-alert medications that most warrant their use. ■ **ISMP does NOT recommend the use of an independent double check for all high-alert medications**, all vulnerable patients (e.g., pediatrics), or all high-risk tasks. ■ Lack of time to carry out the checking process properly is a strong, recurring theme in studies of failed independent double checks and staff resistance to this strategy. ■ Fewer independent double checks strategically placed at the most vulnerable points of the medication use process will be more effective than an overabundance of independent double checks.
Conduct Double Checks Independently
■ An independent double check requires two people to *separately* check the targeted components of the work process, without knowing their colleague's results. ■ If the double check is conducted independently, it reduces the risk of confirmation bias that may occur if the same person prepares and checks a medication. ■ Two people working independently are less likely to make the same mistake; if they work together or suggest what the checker should find, both could follow the same path to an error.
Avoid Sole Reliance on Independent Double Checks
■ Independent double checks can sometimes fail, especially since the process depends on one fallible person assessing another fallible person's work; thus, avoid sole reliance on this strategy. ■ Do not use independent double checks as a means of fixing problems when more fundamental system redesign is needed to prevent errors. ■ Higher leverage strategies (e.g., use of barriers, computer alerts with hard stops, standardization, barcode scanning) should be considered first.
Conduct a Cognitive Review of the Medication
■ Analysis of failed independent double-check processes suggest that double checking often becomes a superficial, routine task, and people may lose sight of its importance. ■ What is often missing in the independent double-check process is the firm belief that everyone—even the most trusted and reliable staff member—is fallible, and a more cognitive review of all components of the medication is necessary. ■ Effective checking requires critical thinking beyond verification of the "5 rights." Is the drug appropriate for the patient? Does the drug's indication match the patient's diagnoses or conditions? Is the dose appropriate for *this* patient? These questions and more need to be answered independently.
Standardize the Process and Provide Tools
■ Variations in how independent double checks are carried out abound, and compliance with all the steps in the process is often inconsistent. ■ To reduce inconsistencies, establish a standard process for carrying out an independent double check and ensure that adequate resources are available to follow this process. ■ Educate staff about the importance of independent double checks and how to carry them out properly, not as a superficial task or "cosigning" requirement, but as a vital cognitive task. ■ Make it easy for practitioners to follow and document the independent double-check process without relying on vigilance and memory (e.g., checklists [electronic or paper]) as a reminder of the components of certain critical processes and/or medications that should be checked.

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We have reported this concern to Teva and the US Food and Drug Administration (FDA). Teva informed us that there already is a plan to change the date format to make it consistent with other products marketed in the US. The company stated that the plan should be implemented "shortly."

Table 1. List of abbreviations used by Teva Canada, along with associated months in French and English.

JA: Janvier – January
FE: Février – February
MR: Mars – March
AL: Avril – April
MA: Mai – May
JN: Juin – June
JL: Juillet – July
AU: Aout – August
SE: Septembre – September
OC: Octobre – October
NO: Novembre – November
DE: Décembre – December

There have been many problems with the way expiration dates are communicated on medical products over the years. For example, on US products, one can find the abbreviation JN or JU, even though these could represent expiration dates in January, June, or July. So, it is time for this ongoing problem to be addressed. The good news is that USP is currently evaluating the need for changes and standards that we believe will take these problems into consideration. FDA is currently updating their guidance for industry as well. We look forward to seeing new standards soon.

Diastat AcuDial—set and lock the dose. The **DIASTAT ACUDIAL** delivery system is a gel formulation of diaze**PAM** intended for rectal administration. It is used to manage select refractory epilepsy in patients on stable antiepileptic drugs who require intermittent use of diaze**PAM** to control bouts of increased seizure activity. The product is available in 10 mg or 20 mg rectal syringes designed to deliver minimum dosages of 5 mg or 12.5 mg respectively,

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the checker should find. Independent double checks are recommended since, if the checker is primed, an error may not be detected due to confirmation bias.[2] Only 3 of the 13 reviewed studies reported if and how independent and primed double checking were differentiated. One of those studies only looked at double checking compliance rates. The other 2 studies, both of good quality, specifically described the double checking performed as independent and found a positive correlation between the independent double check and reduced medication error rates. None of the studies provided rates of medication errors comparing independent versus primed double checking.

All Medications Versus Selected High-Alert Medications

More than half of the studies investigated double checks for all types of medications administered in a hospital. For example, one study required double checking of all medications administered; another study required double checking of all oral, inhaled, and topical medications; and several other studies required double checking of all intravenous medications. Very few studies investigated double checks for only selected high-alert medications, as recommended by ISMP. With workflow issues ever present, lack of time to carry out the checking process properly is a strong, recurrent theme of failed double checks and staff resistance to this strategy. Fewer independent double checks strategically placed at the most vulnerable points of the medication use process will likely be much more effective than an overabundance of independent double checks. However, only 2 studies in the systematic review tested selective double checking for only the most vulnerable high-alert medications (i.e., subcutaneous insulin injections; high-risk drugs).

Areas of Disagreement with Conclusions

Evidence to Support Double Checks

The authors suggest that their review reveals there is no solid evidence base to support the use of double checks. They also raise the question as to whether a lack of association between double checking and drug administration errors is due to an actual lack of effect or a lack of compliance with the intervention itself, a cursory double check, or lack of a truly independent double check. While the latter question is certainly valid, please note that all 7 (2 of which are good quality) of the reviewed studies that actually tested for an association between double checking and medication administration errors demonstrated a reduction in medication errors when a double check was used. Although methodological weaknesses were present in some of the studies, all 7 studies failed to show that single checking led to fewer errors than double checking. While one of the good-quality studies identified situations in which a second more experienced nurse dissuaded the first inexperienced nurse from acting on a suspected error, the overall effect of double checking increased error detection with both complex weight-based dosing errors and a straightforward wrong vial error.[5] While we agree with the authors' conclusion that there is a lack of high-quality studies on the subject of double checking (perhaps this is what the authors meant by "no solid evidence-based support"), we disagree that there is no evidence to support its judicious and proper use.

Speculation about the Potential Prevention of Harm

None of the studies included in the review assessed patient harm as an outcome. Thus, the authors hypothesize as to the potential effect of double checks on actual patient harm, concluding that even a large risk ratio in favor of double checking may not result in a substantial reduction in harm. They go on to question the potential value in using double checks to prevent actual harm, particularly from rare, catastrophic errors. The authors base this conclusion on the fact that, overall, there is a low proportion of medication administration errors that result in actual patient harm. However, ISMP has long recommended reserving double checks for the most vulnerable high-alert medications, which carry a much higher risk of causing catastrophic patient harm when used in error than most other medications. Thus, we respectfully disagree with speculation that the

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with dosage increments of 2.5 mg up to a maximum of either 10 mg or 20 mg. A 2.5 mg syringe is available for pediatrics. Each package contains 2 unlocked rectal syringes.

Before the product is dispensed to patients or patient care areas, pharmacists must dial, set, and lock the syringe according to the prescribed dose, even when the maximum dose has been prescribed. Once dialed and locked, the prescribed dose will appear in the dose display window, and the locking ring, designated with a green "ready" band, will be engaged (**Figure 1**). This helps to prevent the wrong dose from being administered by the caregiver. However, since the introduction of the device in 2005, errors have been reported because the device was not dialed and locked to the proper dose prior to dispensing and administration. We mentioned this issue in our September 7, 2006 and March 27, 2014 newsletters. Since then, the US Food and Drug Administration (FDA) and ISMP have continued to receive reports of Diastat AcuDial being dispensed without the dose set or with the wrong dose dialed and locked.

Given the infrequent use of Diastat in inpatient settings, consider building a computerized alert to remind staff in any setting to check that the dose has been dialed and locked correctly (for BOTH syringes in the pack if dispensed that way). Pharmacists,

Figure 1. After setting the dose of 7.5 mg, for example, and locking the syringe, a green band appears to indicate it is ready for administration.

nurses, patients, and caregivers should be educated about how to use the device, including confirming that the prescribed dose is visible in the display window and the green "ready" band is visible. A useful video is available at: www.ismp.org/ext/293.

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potential value of double checks in preventing actual harm is low; instead, appropriately placed double checks for the most vulnerable high-alert medications can prevent devastating patient harm, and thus offer great value.

Areas of Agreement with Conclusions

ISMP concurs with the authors about the methodological concerns with many of the studies on double checking and the need for future, high-quality research that focuses on:

- Clearly linking independent double checks for select high-alert medications to fewer errors reaching patients and harmful outcomes using measures that do not rely on self-reports of medication error rates or incident report data
- Robust trials measuring the frequency and severity of errors identified and prevented during the double-checking process, and potential and actual outcomes of errors
- Closer attention to the details of the double-checking process used, in particular the extent to which checks are performed independently and whether all steps in the process are completed as specified
- The fundamental questions about when and where double checking, using humans and/or technology, is beneficial to patient safety outcomes

ISMP Conclusions

In general, we disagree with the authors' conclusion that the evidence shows an absence of effectiveness in reducing medication error rates with double checking. In fact, all the studies included in this review that tested for effectiveness showed a reduction of medication error rates with double checking. While we agree that the quality of many of the studies was poor or fair, with methodological weaknesses, this review does not present enough evidence to abandon the use of independent double checks for the most vulnerable high-alert medications. On the contrary, the review should encourage healthcare providers to evaluate their current double check systems to ensure they are designed for success, as outlined in our newsletter article[2] and summarized in **Table 1** (page 2).

Given the extent to which double checks are embedded as part of routine nursing practice, and the considerable costs involved, we agree there is a compelling reason to establish a sound evidence-base for its ongoing use and to inform decisions about when and how it might be most effective to improve medication safety. While one may argue that the current evidence for independent double checking is imperfect, ISMP stands behind our recommendation that, when employed judiciously, conducted properly, and bundled with other strategies, manual independent double checks can be part of a valuable defense to prevent potentially harmful errors from reaching patients.[2]

References

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ISMP recognizes that the use of diazePAM rectal gel may decrease as products are developed to take advantage of intranasal administration. As more clinical trials are published and familiarity with intranasal benzodiazepines—particularly midazolam—increases, diazePAM rectal gel use and accompanying errors may subsequently decline. To date, ISMP has received 2 error reports concerning the intranasal mucosal atomization device (MAD) and no reports regarding the atomized drug itself. The errors with the MAD are related to an issue with an adapter piece and concerns about the luer-lock design and the potential for nonsterile intravenous administration.

HIGH-ALERT

Enoxaparin prefilled syringes. Thank you for responding to our February 28, 2019, request to send us reports about the long-standing quality issues with enoxaparin syringes, including problems with the needle safety mechanism and issues with syringe parts that separate from each other during use. These reports have been sent to the companies and the US Food and Drug Administration (FDA) for investigation and resolution. As this investigation is still underway and involves multiple companies and product strengths, it's important to continue submitting reports that can help inform and prioritize regulatory actions. Thank you!

Special Announcement

Get intensive about medication safety

Don't miss our last ***Medication Safety Intensive*** (MSI) workshop of the year being held in **Las Vegas**, NV, on **December 6-7**! This is a unique opportunity to maximize your error prevention efforts and learn to look at your organization through the eyes of leading safety experts. For details, visit: www.ismp.org/node/127.

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